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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,977	07/22/2002	Roberto Alcantara Martins Zucchetti	32286R009	9118

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EXAMINER	
CHANNAVAJJALA, LAKSHMI SARADA	
ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 12/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/030,977	ZUCCHETTI ET AL.	
	Examiner	Art Unit	
	Lakshmi S Channavajjala	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-20 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-20 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 1/16/2002.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt of IDS and preliminary amendment dated 1-16-02 is acknowledged.

Claims 1-21 are pending.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1 is rejected under 35 U.S.C. 102(b) as being anticipated by US 6,193,956 to Liu et al (Liu).

Liu discloses an antioxidant composition comprising ascorbic acid, propylene glycol, EDTA, carboxyvinyl polymer added in a first water phase and oily phase components and retinol added to the oil phase (see example 1 preparation in col. 15, lines 45-67 and the composition example 1 in col. 16). The oily phase of the composition of Liu recites petrolatum and retinol, which read on the claimed moisturizer and immunomodulator respectively because petrolatum is the same as petroleum jelly, which is a moisturizer, and Liu teaches that retinol is an antioxidant that meets the claimed immunomodulator.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

2. Claims 1, 3, 8-10 and 12-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,902,591 to Herstein.

Herstein teaches stable ascorbic acid composition for the treatment of skin, comprising two components, wherein ascorbic acid is prepared in a powdered phase and added to the second liquid phase (abstract). The liquid phase of the composition includes the claimed components disodium EDTA, superoxide dismutase (reads on immunomodulator), propylene glycol, glycerin (reads on moisturizer of instant claims), lecithin, emulsifiers, etc., (table 1, col. 12). Also for the components and amounts of the compounds in the composition, see col. 1, l 12-40; col. 3, l 8-23; col. 4, l 32-62; col. 10, l 6-23; col. 12-13. With respect to the claimed aqueous phase, Herstein adds ascorbic acid powder to the liquid phase and it is the position of the examiner that due to its water-soluble property, ascorbic acid will be present in the aqueous phase of the composition of Herstein. Herstein fails to teach the claimed ration of the phases as in claim 1 or in claim 8. However, Herstein recognizes the instability of ascorbic acid and accordingly suggests adding separately. Accordingly, optimizing the amounts of ascorbic acid added relative to the other

components of the composition would have been within the scope of a skilled artisan. Herstein also teaches addition of various chelating agents so as to stabilize ascorbic acid composition. Accordingly, even though Herstein fails to teach the specific agents of claim 15, 16, it would have been obvious for a skilled artisan to choose the appropriate chelators such that a stable preparation is obtained.

3. Claims 1-3, 7-10 and 12-21 rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,193,956 to Liu et al in view of US 6,348,200 to Nakajima et al (Nakajima).

Liu teaches stable antioxidant compositions comprising propylene glycol, ascorbic acid, disodium EDTA, and water, in addition to the antioxidants such as vitamin A. Liu teaches addition of chelating agents to each of the oil and water phases, addition of emulsifiers such as cetearyl alcohol and cetearyl glucoside (col. 4), emollients (col. 7), oil soluble antioxidants and water-soluble antioxidants such as sodium bisulfite, ascorbic acid (col. 8, lines 3-10), humectants including glycerol, propylene glycol (col. 8, lines 64-67), moisturizing agents including propylene glycol, allantoin (col. 10, lines 20-28). Example 1 teaches preparing two different phases (oil and water phase) containing respective ingredients and lists the claimed components i.e., propylene glycol, and ascorbic acid, disodium EDTA. Further, the compositions of examples 9B, 12, 13 (col. 27-28), contain allantoin, sodium bisulfite and emulsifiers (col. 6, lines 45-59). Liu teaches propylene glycol as a humectant and skin moisturizer and accordingly optimizing the amount of the same to achieve an art recognized effect would have been obvious for a skilled artisan. Liu teaches the composition containing antioxidants for skin care, in particular skin dryness, leatheriness, wrinkling, etc (col.1). While Liu teaches the composition primarily with

retinoic acid, Liu teaches adding other water-soluble antioxidants such as vitamin C, and as explained the examples of Liu also recite ascorbic acid.

Liu fails to teach the claimed ceramides and betaglycane (also known as glycine betaine). However, Liu recognizes the need of adding emollients such as oil or wax or humectants so as to achieve quick absorption of the composition and also to mitigate skin dryness.

Nakajima teaches compositions for treating skin and improving the water-retaining ability of the horny layer of skin. The composition of Nakajima comprises amide derivatives that are ceramides (formulae of col. 2-3), and at least one polyhydric alcohol. Nakajima teaches ceramides compounds in an amount of 0.001% to 50% (col. 12) and polyhydric alcohols such as butylenes glycol, propylene glycol, in an amount of 0.001% to 50% (col. 12). Nakajima further teaches addition of free radical scavengers such as carotenoids, tocopherol, ascorbic acid etc., for detoxification of peroxides and active oxygen is enhanced and thus improves the skin roughness and smoothness (col. 16, lines 19-39). Nakajima teaches incorporation of a pH adjustor in the skin care composition and among the pH adjustors Nakajima suggests the claimed glycine betaines (col. 25, lines 21-29 and example 14). Nakajima teaches the composition in the form of emulsions, suspensions, as two-layer compositions etc (col. 25). Both Liu and Nakajima teach compositions to treat skin for dryness, roughness. Therefore, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to include the amide compounds i.e., ceramides and pH adjustors such as glycine betaine of Nakajima in the antioxidant composition of Liu comprising ascorbic acid, retinoid, propylene glycol, allantoin, sodium bisulfite, EDTA and other emulsifiers because Nakajima teaches that the water content of horny layer of skin is important for imparting moisture to the skin, maintain the skin smoothness and

softness and that the effect of conventional moisturizers such as humectants is temporary as they remain on the skin to provide water to skin and they do not have the ability to improve the water-retaining ability of the horny layer of skin, which is achieved by adding ceramides along humectants such as glycols. Therefore, a skilled artisan would have expected to improve the moisturizing and smoothness effect of the composition of Liu and also the ability to prevent skin inflammation and skin wrinkling (dermal aging) due to the presence of ceramides.

Claims 4-6 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,193,956 to Liu et al and US 6,348,200 to Nakajima et al (Nakajima) as applied to claims above, and further in view of US 5,470,874 to Lerner.

The teachings of Liu et al and Nakajima et al have been discussed above. None of the references teach claimed proanthocyanidines (PRO).

Lerner teaches a skin care composition comprising ascorbic acid and proanthocyanidines, as the composition possesses a sunscreen and collagen repair properties. Lerner teaches that both vitamin C and proanthocyanidines have superior free radical scavenging properties and are useful in collagen synthesis, optimum maintenance of immune system, etc (col.2). Lerner also teaches addition of propylene glycol, EDTA, xanthan gum etc., in the composition (col. 4). It would have been obvious for one of an ordinary skill in the art at the time of the instant invention to add proanthocyanidines of Lerner to the composition of Liu et al comprising ascorbic acid, together with ceramides and glycine betaine (of Nakajima) because Lerner suggests that both the components have superior antioxidant activity and that a

combination of vitamin C and proanthocyanidines result in an enhanced tissue healing response time, without any irritating side effects and yet long shelf life.

Claims 4-6 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,902,591 to Herstein as applied to claims 1, 3, 8-10 and 12-20 above, and further in view of US 5,470,874 to Lerner and US 6,348,200 to Nakajima et al (Nakajima).

Herstein, discussed above, fails to teach the claimed ceramides, glycine betaine, and proanthocyanins of the instant claims.

Nakajima, as discussed above, teaches compositions for treating skin and improving the water-retaining ability of the horny layer of skin.

Lerner (see above) teaches a skin care composition comprising ascorbic acid and proanthocyanidines, as the composition possesses a sunscreen and collagen repair properties.

Therefore, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to add proanthocyanidines of Lerner to the composition of Herstein comprising ascorbic acid as an active agent because Lerner suggests that both the components have superior antioxidant activity and that a combination of vitamin C and proanthocyanidines result in an enhanced tissue healing response time, without any irritating side effects and yet long shelf life. Further, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to include the amide compounds i.e., ceramides and pH adjustors such as glycine betaine of Nakajima in the antioxidant composition of Herstein comprising ascorbic acid because Nakajima teaches that the water content of horny layer of skin is important for imparting moisture to the skin, maintain the skin smoothness and softness and that the effect of

conventional moisturizers such as humectants is temporary as they remain on the skin to provide water to skin and they do not have the ability to improve the water-retaining ability of the horny layer of skin, which is achieved only by adding ceramides along humectants such as glycols. Therefore, a skilled artisan would have expected to improve the moisturizing and smoothness effect of the composition of Herstein and also the ability to prevent skin inflammation and skin wrinkling (dermal aging) due to the presence of ceramides.

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-21 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 28-45 of copending Application No. 10/030,983. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant set of claims and the copending claims recite a composition comprising primarily an antioxidant, and a metallic ion-sequestering agent, a deoxygenating agent (which is claimed as a oxidation reaction reverting agent in the instant claims). The copending claims recite the same specific metallic ion-sequestering agent, a

deoxygenating agents as in the instant claims. Further, the copending claims also recite PRO and ceramides in the composition, which are also claimed in the instant application. Both sets of claims also recite two-phase compositions. Instant claims recite a specific ratio of the first and second phases of the composition, which is different from the claimed ratio in the copending claims. However, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to prepare the claimed two-phase composition comprising antioxidant, sequestering agent, oxidation reverting agent and other ceramides by optimizing the ratio of both the phases that constitute the composition so as to achieve a stable antioxidant composition with an expectation to achieve the desired antioxidant activity.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-21 are directed to an invention not patentably distinct from claims 1-45 of commonly assigned 10/030,983. Specifically, both sets of claims, as explained, are directed to antioxidant composition comprising the same sequestering agents, moisturizers, reducing agents etc (see above).

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302). Commonly assigned 10/030,983, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting

inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

Claim Rejections - 35 USC § 112

8. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims 2, 4, 5, 6, and 21 recite the broad recitation of the percentages of specific components, and the claims also recite a narrower percentage of the components. Further, claim 13 recites glycols and most preferably propylene glycol that is broad limitation followed by a narrow limitation.

9. Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Instant claim recites sequestering compounds, group that comprises phosphonates, which include di, tri, tetra and pentavalent acids. It is unclear to the examiner if the phosphonate compounds are different from the acids of different valencies or if the acids form the phosphonate. Clarification is requested.

10. Examiner notes typographical errors throughout the claims, such as butyline glycol, betaglycane and deoxigenatyng or deoxygenating compounds and requests applicants to correct the same.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 7.30 AM -4.00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lakshmi S Channavajjala
Examiner
Art Unit 1615
December 4, 2004